K122796

Special 510(k): Device Modification
CXI™ Support Catheter
Cook Incorporated
11 September 2012

OCT 11 2012

510(k) SUMMARY

Submitted By: Molly Busenbark, MA, RAC
Cook Incorporated
750 Daniels Way
Bloomington, IN 47404

Device:

Trade Name: CXI™ Support Catheter
Proposed Classification: Catheter, Continuous Flush
KRA (21 CFR §870.1210)

Indications for Use:

The CXI™ Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.

Predicate Device:

Cook Incorporated's CXI™ Support Catheter is identical in terms of intended use and similar in terms of principles of operation, materials of construction, and technological characteristics to the predicate devices. The device, subject of this submission, is substantially equivalent to the CXI™ Support Catheter and the CrossCath™ Support Catheter, manufactured by Cook Incorporated, which are cleared under 510(k) numbers K072724 and K093052, respectively.

Comparison to Predicate Device:

It has been demonstrated that the CXI™ Support Catheter is comparable to the predicate devices in terms of design, intended use, materials, fundamental technology, and principal of operation.

Device Description:

The CXI™ Support Catheter consists of a 2.3, 2.6, or 4.0 French catheter with hydrophilic coating. The catheter includes four (4) radiopaque markers to assist in fluoroscopic visualization of the catheter during use. The 2.3, 2.6, or 4.0 French catheters allow acceptance of a 0.014 inch diameter (0.36 millimeters) wire guide, a 0.018 inch diameter (0.45 millimeters) wire guide, or a 0.035 inch diameter (0.89 millimeters) wire

guide, respectively. The catheter is available in four lengths: 65, 90, 135, and 150 cm, with a straight or angled distal tip.

Test Data:

The following tests were performed to demonstrate that the CXI™ Support Catheter meets applicable design and performance requirements and supports a determination of substantial equivalence. Additionally, appropriate engineering tests were also performed on aged product to ensure that the CXI™ Support Catheter meets the performance requirements throughout the duration of shelf life.

- Tensile Strength – Testing shows the tensile strength during proper clinical use should not fracture or rupture the catheter. In conformance with the applicable sections of ISO 10555-1, the predetermined acceptance criteria were met.
- Liquid Leakage – Testing shows there would be no liquid leakage from the catheter during proper clinical use. In conformance with the applicable sections of ISO 10555-1, the predetermined acceptance criteria were met.
- Static Burst – Testing shows the pressures reached during proper clinical use (maximum pressure at maximum flow rate) are less than the static burst pressure of the catheter, and should not fracture or rupture the catheter. The predetermined acceptance criteria were met.
- Dynamic Burst – Testing shows the pressures reached during proper clinical use (maximum pressure at maximum flow rate) are less than the dynamic burst pressure of the catheter, and should not fracture or rupture the catheter. The predetermined acceptance criteria were met.
- Flow Rate – Testing shows the pressure exerted at the maximum flow rate during proper clinical use should not fracture or rupture the catheter. The predetermined acceptance criteria were met.
- Biocompatibility – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, hemolysis, pyrogen, partial thromboplastin time, and complement activation) shows the device is biocompatible. In conformance with the applicable sections of ISO 10993-1, the predetermined acceptance criteria were met.

In conclusion, the results of these tests provide reasonable assurance that the device is as safe and effective as the predicate devices and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 11 2012

Cook Incorporated
c/o Molly Busenbark
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47402-0489

Re: K122796
Trade/Device Name: CXI Support Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: September 11, 2012
Received: September 12, 2012

Dear Ms. Busenbark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K122796

Device Name: CXI™ Support Catheter

Indications for Use for the CXI™ Support Catheter:

The CXI™ Support Catheter is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.

Prescription Use XX OR Over-the-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122796